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# Updated Checklist of Confidential Information

## To be completed at time of submitting Company Comments on the NDC Detailed Advice Document

|  |  |
| --- | --- |
| Approved name of medicinal product: |  |
| Brand name: |  |
| Company: |  |

Does the New Product Assessment Form (NPAF) or Company Comments document contain any confidential information? (Please check appropriate box). Note that for the NPAF only changes to the confidential information already provided are required:

No [ ]

Yes [ ]

If yes, please complete the table below in full (insert or delete rows as necessary) and ensure that relevant sections of the NPAF/Company Comment document are clearly highlighted and underlined, and match the information provided in the table.

|  |  |  |  |
| --- | --- | --- | --- |
| Page number\* | Nature of confidential information | Rationale for confidential status | Timeframe of confidentiality restriction**‡** |
|  | [ ]  Commercial in confidence†[ ]  Academic in confidence† |  |  |
|  | [ ]  Commercial in confidence†[ ]  Academic in confidence† |  |  |

\* Reference page(s) of your NPAF/Company Comment where the confidential information appears.

† Check box as appropriate

‡Please state whether the timeframe given is exact or approximate. For academic in confidence material, state either the date and title of the conference at which the information will be made public, or the date of submission and title of the journal to which the relevant paper has been submitted, together with the journal’s stated turnaround time. If the conference or journal details are not finalised, state the company’s commitment to publish and the target date for the same.

As agreed with ABPI, academic in confidence information may be presented verbally during the public sessions of the SMC meetings. Please indicate in the table above if this is not acceptable (e.g. if the data belong to a third party).

## Patient Access Schemes (PAS)

Is the medicine subject to a confidential PAS? No [ ]  Yes [ ]

If Yes, I confirm that appropriate reference to the with-PAS ICERs can be made at the SMC meeting and included in the final published SMC advice (please check appropriate box):

Yes [ ]

\*No [ ]

\*If No, detail reason in table above